

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***  
**75-175**

**MICROBIOLOGY REVIEW**

OFFICE OF GENERIC DRUGS  
Microbiologists Review #2  
February 19, 1999

A. 1. ANDA: 75-175

APPLICANT: Roxane Laboratories, Inc.  
Attention Sean Alan F.X. Reade  
1809 Wilson Road  
Columbus, OH 43228

2. PRODUCT NAME:  
**Chromolyn Sodium Inhalation Solution USP**
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10 mg/mL,  
2 mL unit dose vial.
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Bronchodilator

B. 1. DATE OF INITIAL SUBMISSION:

July 25, 1997 (received July 28, 1997)

2. DATE OF AMENDMENT: **January 19, 1999 - Subject of  
this Review.**

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: February 12, 1999.

*December 17, 1998*  
*6/22/99*

C. REMARKS: Roxane has asked for long term bulk drug product storage (30 days) and long term days) of this drug product. Chromolyn Sodium is known to have had a \_\_\_\_\_ because of long term \_\_\_\_\_. Roxane addressed this problem by using a \_\_\_\_\_ instead of the normal \_\_\_\_\_ and by storing the product at \_\_\_\_\_. This poses other problems such as growth promotion testing at higher temperatures.

D. CONCLUSIONS: The submission is not recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiologist's Draft of Letter to Applicant".

*/s/*

James L. McVey

initialed by M. Fanning *MF* 2/22/99.

cc:

Page(s) 7

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Commercial/Confidential  
Information and are not  
releasable.

2/19/99

Micro Review 2

OFFICE OF GENERIC DRUGS  
Microbiologists Review #1  
April 22, 1998

A. 1. ANDA: 75-175

APPLICANT: Roxane Laboratories, Inc.  
Attention Sean Alan F.X. Reade  
1809 Wilson Road  
Columbus, OH 43228

2. PRODUCT NAME:

**Chromolyn Sodium Inhalation Solution USP**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10 mg/mL,  
2 mL unit dose vial.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Brochodilator

B. 1. DATE OF INITIAL SUBMISSION:

**July 25, 1997 (received July 28, 1997)**

2. DATE OF AMENDMENT: NA

3. RELATED DOCUMENTS: NA

4. ASSIGNED FOR REVIEW: March 31, 1998

C. REMARKS:

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D. CONCLUSIONS: The submission is not recommended for  
approval on the basis of sterility assurance. Specific  
comments are provided in "E. Review Notes" and  
"Microbiologist's Draft of Letter to Applicant".

/S/  
James L. McVey

initialed by R. Patel

*R. Patel 4/23/98*

cc:

Page(s) 15

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releasable.

4/22/98

Micro Review 1

OFFICE OF GENERIC DRUGS

Microbiologists Review #3

August 20, 1999

A. 1. ANDA:       **75-175**

APPLICANT:       Roxane Laboratories, Inc.  
                  Attention Sean Alan F.X. Reade  
                  1809 Wilson Road  
                  Columbus, OH    43228

2. PRODUCT NAME:

**Cromolyn Sodium Inhalation Solution USP**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10 mg/mL,  
2 mL unit dose vial.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Brochodilator

B. 1. DATE OF INITIAL SUBMISSION: July 25, 1997  
(Received July 28, 1997)

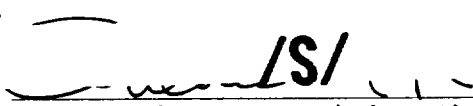
2. DATE OF FAX AMENDMENT: June 28, 1999  
**Subject of This Review (Received June 29, 1999)**  
[Microbiology Queue date for "Received" is June 28, 1999]

3. RELATED DOCUMENTS: NA

4. ASSIGNED FOR REVIEW:    8/18/99

C. REMARKS: The subject FAX amendment provides for the response to the microbiology deficiencies in the correspondence dated June 1, 1999.

D. CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes".

 **LS/** 7/25/99  
Andrea S. High, Ph. D.

cc:

rorev\75-175a2 7/25/99

Page(s) 2

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8/25/99

Micro Review 3